Originally Filed: November 27, 2024
Redacted Version Filed: December 4, 2024

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	REDACTED - PUBLIC VERSION C.A. No. 21-1015 (JLH) [redacted] [redacted]
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	

SAREPTA'S LETTER TO THE HONORABLE JENNIFER L. HALL REGARDING RESPONSE TO NS'S MOTION TO STRIKE (D.I. 640)

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc and The University of Western Australia.

OF COUNSEL:

Charles E. Lipsey
J. Derek McCorquindale
Ryan P. O'Quinn
L. Scott Burwell
Jameson K. Gardner
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
1875 Explorer Street, Suite 800
Reston, VA 20190-6023
(571) 203-2700

William B. Raich
Michael J. Flibbert
John M. Williamson
Yoonhee Kim
Yoonjin Lee
Kaitlyn S. Pehrson
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Alissa K. Lipton
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
Two Seaport Lane
Boston, MA 02210-2001
(617) 646-1600

Amanda P. Reeves
Anna M. Rathbun
Graham B. Haviland
Michael A. Morin
David P. Frazier
Rebecca L. Rabenstein
Bornali Rashmi Borah
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, D.C. 20004
(202) 637-2200

Ernest Yakob
Rachel Renee Blitzer
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020
(212) 906-1200

Michele D. Johnson
LATHAM & WATKINS LLP
650 Town Center Drive, 20th Floor
Costa Mesa, CA 92626
(714) 540-1235

Will Orlady
LATHAM & WATKINS LLP
10250 Constellation Blvd., Suite 1100
Los Angeles, CA 90067
(424) 653-5500

Michele D. Johnson
LATHAM & WATKINS LLP
650 Town Center Drive, 20th Floor
Costa Mesa, CA 92626
(714) 540-1235

November 27, 2024

Dear Judge Hall:

We write on behalf of Sarepta Therapeutics, Inc. ("Sarepta") and the University of Western Australia ("UWA") in response to Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd.'s and Counter-Defendant NS Pharma, Inc.'s (collectively, "NS") Motion to Strike (D.I. 640) and supporting Letter Brief (D.I. 641). For the reasons below, the Court should deny NS's unjustified request to strike and exclude ¶¶ 14-20 of John Jarosz's Second Supplemental Expert Report.

I. THE CHALLENGED PARAGRAPHS OFFER NO NEW OPINIONS

Contrary to NS's arguments, Mr. Jarosz offers no new opinions in the challenged paragraphs. Those paragraphs are not legal opinions, or "opinions" at all—they instead provide context for Mr. Jarosz's damages opinions, including those expressed in ¶¶ 21-22, which NS has not moved to strike. Mr. Jarosz identifies and summarizes the agreements he considered in forming his ultimate damages opinions, including how they informed the assumptions on which he necessarily relied for those opinions. But Mr. Jarosz does not stray into legal interpretation; he merely explains his understanding of the facial terms of the agreements and how that relates to his ultimate damages opinions.[1] *Id.* at ¶¶ 17-22 (explaining how Sarepta understands the agreements to operate and his "understand[ing of] Counter-Defendants' theory" to the contrary, both of which are accounted for in his calculations). Such background is not only acceptable but is a necessary and common practice for damages experts. *Shelton v. Apex Surgical, LLC*, No. CIV-08-01087-HE, 2009 WL 10672608, at *4 (W.D. Okla. Nov. 12, 2009) ("There is, of course, nothing wrong with a damages expert . . . making certain assumptions upon which further calculations are based.").

In fact, both Mr. Jarosz ***and*** NS's damages expert, Mark Hosfield, included similar context for the other agreements considered in their earlier reports in this case. *See, e.g.,* Ex. B at 21 [redacted] 23 [redacted] 30-31 [redacted]; Ex. C at ¶¶ 140 [redacted], 143 [redacted].

NS's arguments that Mr. Jarosz offers opinions about the legal operation of the [redacted] and "improperly interprets contractual terms" hold no water. D.I. 641 at 1. Nowhere in the cited paragraphs does Mr. Jarosz express any opinions on the operation of the agreements. Thus, there are no opinions to exclude. *XY, LLC v. Trans Ova Genetics, LC*, No. 13-CV-0876-WJM-NYW, 2016 WL 97788, at *6–7 (D. Colo. Jan. 8, 2016) (declining to exclude statements from a damages expert report "stating assumptions or data on which [the expert] relied in calculating the scope of damages" but excluding the statement "it is my opinion that [the

[1] Sarepta made clear in connection with the meet-and-confer process preceding NS's request that Mr. Jarosz was not offering any opinions on contract interpretation, and offered to amend the language of Mr. Jarosz's report to the extent NS believed it needed to be clarified. NS rejected Sarepta's offer sight unseen and filed this motion hours later. Ex. A.

defendant] was in breach"). Other courts have found that similar language in the context of a damages report is not only acceptable, but necessary for the expert to form his or her ultimate opinions. *Rowe v. DPI Specialty Foods, Inc.*, No. 2:13-CV-00708-DN-DJF, 2015 WL 4949097, at *5 (D. Utah Aug. 19, 2015), *aff'd in part*, 727 F. App'x 488 (10th Cir. 2018) ("it is necessarily the role of a damages expert to offer an opinion based only on assumptions because . . . [u]ntil a jury has found facts to resolve the factual issues presented to them, an expert has nothing other than assumptions on which economic analysis may be based."). Mr. Jarosz's statements providing context and explaining his assumptions are both acceptable and expected. NS will have the opportunity to cross-examine Mr. Jarosz as to the basis for his understanding of the agreements. *See XY, LLC*, 2016 WL 97788, at *6–7 (denying motion to exclude "assumptions or data on which [the damages expert] relied in calculating the scope of damages, not [] his own claim to definitive interpretations of the License Agreement" and noting that the expert "will be subject to cross-examination"). NS's request to exclude these statements should be denied.

Ironically, NS's own expert, Mr. Hosfield, made analogous updates based on new NS documents. Subsequent to the production of the [redacted], on May 8, 2024, NS produced [redacted] evidence that NS apparently believes supports its damages positions. In his November 12 Second Supplemental Expert Report, Mr. Hosfield addressed that evidence, as well as evidence produced earlier but about which he had not previously opined. *See* Ex. D at 1 n.1. Notably, Mr. Hosfield did not limit his comments to his understanding of the documents, but went as far as opining that [redacted] *Id.* Sarepta is not seeking to strike this portion of Mr. Hosfield's recent report; Sarepta will deal with it through cross examination at trial. NS should do the same.

II. EXCLUSION IS NOT WARRANTED ON THESE FACTS

Contrary to NS's representations, Mr. Jarosz's statements describing his understanding of the relevant agreements and his resulting assumptions are no surprise and do not prejudice NS. Sarepta's position, which is the basis for Mr. Jarosz's statements, was identified in May 2024, during the parties' dispute over these agreements. *See* D.I. 568; D.I. 572. Since then, NS has had every opportunity to pursue the discovery to which it now says it is entitled. Evaluating the governing *Pennypack* factors establishes that exclusion is not warranted.

Factor 1 (prejudice or surprise): NS has suffered no prejudice or surprise. First, NS argues that it has not had the opportunity to take fact discovery on the relevant agreements and issues, or of Peter Walsh. But NS has known about these documents and positions, including the information described in Mr. Walsh's declaration, since May. *See* D.I. 572. And it is routine for damages experts to speak with employees of the parties to gain understanding of corporate practices without those employees becoming witnesses; indeed, Mr. Hosfield did so. *See* Ex. B at 5 (identifying discussions with [redacted], neither of whom were deposed or identified as witnesses in this case). When, as here, a party decides against taking discovery, it cannot later claim surprise and prejudice. *Bayer HealthCare LLC v. Baxalta Inc.*, No. 16-1122-RGA, 2019 WL 297039, at *2 (no substantial prejudice when movant's expert was able to consider the later-produced documents and movant had the opportunity to conduct relevant fact discovery, but refused); *DeMarines v. KLM Royal Dutch Airlines*, 580 F.2d 1193, 1202 (3d Cir. 1978) (no substantial prejudice when movant was aware of the basic substance of the witness's testimony). Moreover, although NS objects that Mr. Jarosz's supplementation improperly exceeded the scope

of "supplemental financial information," it ignores that NS itself insisted, in a footnote to the parties' proposed amended schedule, to make the supplemental reports "[s]ubject to resolution of the issues raised by Nippon Shinyaku and NS Pharma's Letter Brief Regarding Late Produced Licensing and No Lost Profits (D.I. 568) and Sarepta's response (D.I. 572)." *See* D.I. 597. [redacted] Ex. E at 2-4, 14-19; D.I. 641-1 at ¶¶ 21-22. These calculations make no sense except in the context of the relevant agreements and the parties' positions. Accordingly, not only did NS provide for discussion of these issues in the supplemental damages expert reports, it took advantage of the chance to do so. Additionally, although NS claims to be prejudiced by lack of "opportunity to take discovery relating to [redacted]" (which it chose not to pursue) and that Mr. Jarosz's opinion somehow "backdoor[s]" that evidence, NS fails to mention NS's own newly produced [redacted] evidence or Mr. Hosfield's addressing of [redacted] for the first time in his Second Supplemental Expert Report.

Factors 2 (ability to cure) and 3 (orderly and efficient trial): As explained above, NS had the opportunity to cure any possible prejudice through additional discovery, but chose not to pursue it in the supplemental scheduling order or thereafter during the ensuing six months of additional supplemental discovery. NS cannot now claim that Mr. Jarosz's consideration of the contents and existence of these agreements would disrupt trial. NS will have the opportunity to address the agreements, related positions, and Mr. Jarosz's ultimate damages opinions at trial. *See Bayer HealthCare*, 2019 WL 297039 at *2 (finding the second factor weighed against exclusion and the third factor was neutral when movant's expert was able to consider the later-produced documents, movant refused the opportunity to conduct relevant fact discovery, and movant would have the opportunity to address the documents and related issues at trial).

Factor 4 (bad faith/willfulness): Courts reserve finding willfulness or bad faith for "clear, egregious examples of misconduct." *Glaxosmithkline LLC v. Glenmark Pharms. Inc*., No. 14-877-LPS-CJB, 2017 WL 11685418, at *10 (D. Del. Jan. 20, 2017). There is no such misconduct here. Sarepta complied with the supplemental scheduling order—proposed by NS—diligently and in good faith. NS argues that ***Sarepta*** should have sought further discovery or take some other, undefined action in response to NS's "concerns," but it was plainly NS's obligation to request any discovery it believed necessary. NS now asks this court to penalize Sarepta for NS's own decision not to seek discovery.

Factor 5 (importance): The fifth *Pennypack* factor "is often the most significant factor" in the analysis. *See, e.g.*, *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 298 (3d Cir. 2012) (citation omitted). Expert testimony is necessary to establish damages in this case. The paragraphs identified in Mr. Jarosz's report identify the source of his assumptions upon which his ultimate damages opinions are based. For the factfinder here—the jury—these statements provide important context and should not be excluded. *Masimo Corp. v. Philips Elec. N. Am. Corp.*, No. 09-80-LPS-MPT, 2016 WL 4394359, at *1 (D. Del. Aug. 15, 2016) (fifth factor weighs against exclusion when expert testimony would assist the jury); *Taylor v. S.E. Penn. Transp. Auth*., No. CV 23-2140-KSM, 2024 WL 3205209, at *9 (E.D. Pa. June 27, 2024) (fifth factor weighs against exclusion when expert testimony would provide "important context for the jury").

Mr. Jarosz's statements are contextual and substantially justified. Thus, no exclusion is warranted under Rule 37(c)(1).

The Honorable Jennifer L. Hall
November 27, 2024

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/rah

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via electronic mail)

EXHIBIT A

From: Rebecca.Rabenstein@lw.com
To: amanda.williamson@morganlewis.com; michael.sikora@morganlewis.com; JBlumenfeld@morrisnichols.com; BChard@morrisnichols.com; Lipsey, Charles; Raich, William; Lipton, Alissa; Michael.Morin@lw.com; David.Frazier@lw.com; Ernest.Yakob@lw.com; mdellinger@morrisnichols.com; McCorquindale, J. Derek; Flibbert, Michael; Kim, Yoonhee; Lee, Yoonjin; O"Quinn, Ryan; Burwell, Scott; Williamson, John; Pehrson, Kaitlyn; Amanda.Reeves@lw.com; Anna.Rathbun@lw.com; Graham.Haviland@lw.com; Cremer, John (DC); Will.Orlady@lw.com; Rashmi.Borah@lw.com; michele.johnson@lw.com; Kozikowski, John; SareptaNippon.LWTEAM@lw.com
Cc: NSDistrictCourt@morganlewis.com
Subject: RE: NS/Sarepta, No. 1:21-cv-01015-JLH - Follow-Up To Yesterday"s Meet and Confer
Date: Friday, November 22, 2024 11:15:40 AM
Attachments: shield-advisory.png
chevron-light.png

External email >

Amanda, Mike, and Amy,

Thank you for speaking with us just now regarding your proposed motion to strike certain paragraphs of Mr. Jarosz's Nov. 5 Second Supplemental Expert Report. As we discussed, we explained that Mr. Jarosz was not offering legal interpretations of contracts, but rather was doing what both experts have done through the case in commenting on the content and substance of various agreements. We explained that Mr. Hosfield has done the same thing in his Second Supplemental Expert Reports in opining on the content of NS's late produced [redacted]

In the interest of not burdening the Court and to the extent you thought this unclear, we offered to make edits to the paragraphs to make clear that Mr. Jarosz is not making a legal interpretation of the contracts. We offered to send you this proposed amended language today and serve an amended report. Without even seeing this language, you stated that this would not be sufficient for your purposes and that you still intend to file your letter motion. We nevertheless have included our proposed clarifying edits to Mr. Jarosz's report at the end of this email for your consideration.

Separately, you raised for the first time on the meet and confer your contention that the paragraphs of Mr. Jarosz's report that you are challenging went "far beyond" the supplementation allowed for in the case, which was limited solely to financial information. We explained that we disagree that there was such a limit (indeed, we sought clarity from you on this scope previously and you refused to limit the scope), and added that your own expert, Mr. Hosfield, likewise went beyond what you now assert is the limited permissible scope of these reports because he discussed the content of NS's late produced [redacted]. We also pointed out that NS withheld these agreements and only added them in the days before the May 2024 scheduled trial, despite [redacted] In fact, NS produced these agreements on May 8, 2024, which is two days ***after*** the Pretrial Conference and ***after*** Sarepta produced its agreements that you assert were belatedly produced. Those agreements were both available prior to Mr. Hosfield's First Supplemental and First Supplemental Rebuttal Reports, but he did not opine on them at that time. Mr. Hosfield further opines that these documents [redacted] Neither document states that conclusion, as [redacted]. If Mr. Jarosz's straightforward summaries of production documents are objectionable, Mr. Hosfield's legal interpretations of [redacted] are as well. Unlike NS, however, Sarepta and UWA will

address any disagreements with Mr. Hosfield's opinions via cross examination at trial, not by burdening the Court.

We understand that despite our offers and attempt to not burden the Court with this dispute, you plan to file your letter motion to strike. We will oppose.

Best,
Reba

Proposed clarifying edits (highlighted) to Mr. Jarosz's Nov. 5 Second Supplemental Expert Report:

17. I understand from a conversation with [redacted] that [redacted]

18. Although [redacted] I understand that Counter-Defendants have alleged, as a result, Sarepta suffered no injury-in-fact and cannot seek or recover lost profits damages for the [redacted] time period.[39] As I understand Counter-Defendants' theory, they claim that since [redacted]

20. Even if Counter-Defendants are correct that [redacted]

Rebecca (Reba) L. Rabenstein, Ph.D.
Pronouns: She/Her/Hers

LATHAM & WATKINS LLP
555 Eleventh Street, NW | Suite 1000 | Washington, D.C. 20004-1304

D: +1.202.637.2353 | M: +1.202.803.1415 | Bio

From: Williamson, Amanda S. <amanda.williamson@morganlewis.com>
Sent: Thursday, November 21, 2024 6:04 PM
To: Rabenstein, Reba (DC) <Rebecca.Rabenstein@lw.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>; JBlumenfeld@morrisnichols.com; BChard@morrisnichols.com; charles.lipsey@finnegan.com; William.Raich@finnegan.com; Alissa.Lipton@finnegan.com; Morin, Mike (DC) <Michael.Morin@lw.com>; Frazier, David (DC) <David.Frazier@lw.com>; Yakob, Ernest (NY) <Ernest.Yakob@lw.com>; mdellinger@morrisnichols.com; Derek.McCorquindale@finnegan.com; michael.flibbert@finnegan.com; Yoonhee.Kim@finnegan.com; Yoonjin.Lee@finnegan.com; Ryan.O'Quinn@finnegan.com; scott.burwell@finnegan.com; John.Williamson@finnegan.com; Kaitlyn.Pehrson@finnegan.com; Reeves, Mandy (DC) <Amanda.Reeves@lw.com>; Rathbun, Anna (DC) <Anna.Rathbun@lw.com>; Haviland, Graham (DC) <Graham.Haviland@lw.com>; Cremer, John (DC) <John.Cremer@lw.com>; Orlady, Will (CC) <Will.Orlady@lw.com>; Borah, Rashmi (DC) <Rashmi.Borah@lw.com>; Johnson, Michele (OC) <michele.johnson@lw.com>; John.Kozikowski@finnegan.com; #C-M Sarepta - Nippon - LW TEAM <SareptaNippon.LWTEAM@lw.com>
Cc: NS District Court <NSDistrictCourt@morganlewis.com>
Subject: RE: NS/Sarepta, No. 1:21-cv-01015-JLH - Follow-Up To Yesterday's Meet and Confer

Reba,

That works for us. I will send a meeting invite to you Meagan. Please distribute amongst the relevant members of your team.

Regards,
Amanda

Amanda S. Williamson
Morgan, Lewis & Bockius LLP
110 North Wacker Drive, Suite 2800 | Chicago, IL 60606-1511
Direct: +1.312.324.1450 | Main: +1.312.324.1000 | Fax: +1.312.324.1001
Assistant: Eman Abulhab | +1.312.324.1455 | eman.abulhab@morganlewis.com
amanda.williamson@morganlewis.com | www.morganlewis.com

From: Rebecca.Rabenstein@lw.com <Rebecca.Rabenstein@lw.com>
Sent: Thursday, November 21, 2024 4:16 PM
To: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>; JBlumenfeld@morrisnichols.com; BChard@morrisnichols.com; charles.lipsey@finnegan.com; William.Raich@finnegan.com; Alissa.Lipton@finnegan.com; Michael.Morin@lw.com; David.Frazier@lw.com; Ernest.Yakob@lw.com; mdellinger@morrisnichols.com; Derek.McCorquindale@finnegan.com; michael.flibbert@finnegan.com; Yoonhee.Kim@finnegan.com; Yoonjin.Lee@finnegan.com; Ryan.O'Quinn@finnegan.com; scott.burwell@finnegan.com; John.Williamson@finnegan.com; Kaitlyn.Pehrson@finnegan.com; Amanda.Reeves@lw.com; Anna.Rathbun@lw.com; Graham.Haviland@lw.com; John.Cremer@lw.com; Will.Orlady@lw.com; Rashmi.Borah@lw.com; michele.johnson@lw.com;

John.Kozikowski@finnegan.com; SareptaNippon.LWTEAM@lw.com
Cc: NS District Court <NSDistrictCourt@morganlewis.com>
Subject: RE: NS/Sarepta, No. 1:21-cv-01015-JLH - Follow-Up To Yesterday's Meet and Confer

[EXTERNAL EMAIL]
Amanda,

Further to your request below, we are available tomorrow morning at 10 am Eastern / 9 am Central to meet and confer about your proposed letter motion to strike. Please send us dial-in information.

Best,
Reba

Rebecca (Reba) L. Rabenstein, Ph.D.
Pronouns: She/Her/Hers

LATHAM & WATKINS LLP
555 Eleventh Street, NW | Suite 1000 | Washington, D.C. 20004-1304
D: +1.202.637.2353 | M: +1.202.803.1415 | Bio

From: Williamson, Amanda S. <amanda.williamson@morganlewis.com>
Sent: Thursday, November 21, 2024 11:07 AM
To: Rabenstein, Reba (DC) <Rebecca.Rabenstein@lw.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>; JBlumenfeld@morrisnichols.com; BChard@morrisnichols.com; charles.lipsey@finnegan.com; William.Raich@finnegan.com; Alissa.Lipton@finnegan.com; Morin, Mike (DC) <Michael.Morin@lw.com>; Frazier, David (DC) <David.Frazier@lw.com>; Yakob, Ernest (NY) <Ernest.Yakob@lw.com>; mdellinger@morrisnichols.com; Derek.McCorquindale@finnegan.com; michael.flibbert@finnegan.com; Yoonhee.Kim@finnegan.com; Yoonjin.Lee@finnegan.com; Ryan.O'Quinn@finnegan.com; scott.burwell@finnegan.com; John.Williamson@finnegan.com; Kaitlyn.Pehrson@finnegan.com; Reeves, Mandy (DC) <Amanda.Reeves@lw.com>; Rathbun, Anna (DC) <Anna.Rathbun@lw.com>; Haviland, Graham (DC) <Graham.Haviland@lw.com>; Cremer, John (DC) <John.Cremer@lw.com>; Orlady, Will (CC) <Will.Orlady@lw.com>; Borah, Rashmi (DC) <Rashmi.Borah@lw.com>; Johnson, Michele (OC) <michele.johnson@lw.com>; John.Kozikowski@finnegan.com; #C-M Sarepta - Nippon - LW TEAM <SareptaNippon.LWTEAM@lw.com>
Cc: NS District Court <NSDistrictCourt@morganlewis.com>
Subject: RE: NS/Sarepta, No. 1:21-cv-01015-JLH - Follow-Up To Yesterday's Meet and Confer

Reba,

Attached.

Amanda

Amanda S. Williamson
Morgan, Lewis & Bockius LLP
110 North Wacker Drive, Suite 2800 | Chicago, IL 60606-1511

Direct: +1.312.324.1450 | Main: +1.312.324.1000 | Fax: +1.312.324.1001
Assistant: Eman Abulhab | +1.312.324.1455 | eman.abulhab@morganlewis.com
amanda.williamson@morganlewis.com | www.morganlewis.com

From: Rebecca.Rabenstein@lw.com <Rebecca.Rabenstein@lw.com>
Sent: Thursday, November 21, 2024 8:38 AM
To: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>; JBlumenfeld@morrisnichols.com; BChard@morrisnichols.com; charles.lipsey@finnegan.com; William.Raich@finnegan.com; Alissa.Lipton@finnegan.com; Michael.Morin@lw.com; David.Frazier@lw.com; Ernest.Yakob@lw.com; mdellinger@morrisnichols.com; Derek.McCorquindale@finnegan.com; michael.flibbert@finnegan.com; Yoonhee.Kim@finnegan.com; Yoonjin.Lee@finnegan.com; Ryan.O'Quinn@finnegan.com; scott.burwell@finnegan.com; John.Williamson@finnegan.com; Kaitlyn.Pehrson@finnegan.com; Amanda.Reeves@lw.com; Anna.Rathbun@lw.com; Graham.Haviland@lw.com; John.Cremer@lw.com; Will.Orlady@lw.com; Rashmi.Borah@lw.com; michele.johnson@lw.com; John.Kozikowski@finnegan.com; SareptaNippon.LWTEAM@lw.com
Cc: NS District Court <NSDistrictCourt@morganlewis.com>
Subject: RE: NS/Sarepta, No. 1:21-cv-01015-JLH - Follow-Up To Yesterday's Meet and Confer

[EXTERNAL EMAIL]
Amanda,

We noticed that the draft pretrial order cover pleading that you sent us appears to have some internal comments from/to your team. As such, we are deleting the draft that you sent us last night.

Can you please send us a revised version without those comments in it? Please send it as quickly as you can so that we have time to make our counter edits before the deadline to file tomorrow.

Best,
Reba

Rebecca (Reba) L. Rabenstein, Ph.D.
Pronouns: She/Her/Hers

LATHAM & WATKINS LLP
555 Eleventh Street, NW | Suite 1000 | Washington, D.C. 20004-1304
D: +1.202.637.2353 | M: +1.202.803.1415 | Bio

From: Williamson, Amanda S. <amanda.williamson@morganlewis.com>
Sent: Wednesday, November 20, 2024 10:37 PM
To: Rabenstein, Reba (DC) <Rebecca.Rabenstein@lw.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>; JBlumenfeld@morrisnichols.com; BChard@morrisnichols.com; charles.lipsey@finnegan.com; William.Raich@finnegan.com; Alissa.Lipton@finnegan.com; Morin, Mike (DC) <Michael.Morin@lw.com>; Frazier, David (DC) <David.Frazier@lw.com>; Yakob, Ernest (NY) <Ernest.Yakob@lw.com>; mdellinger@morrisnichols.com; Derek.McCorquindale@finnegan.com; michael.flibbert@finnegan.com; Yoonhee.Kim@finnegan.com; Yoonjin.Lee@finnegan.com;

Ryan.O'Quinn@finnegan.com; scott.burwell@finnegan.com; John.Williamson@finnegan.com; Kaitlyn.Pehrson@finnegan.com; Reeves, Mandy (DC) <Amanda.Reeves@lw.com>; Rathbun, Anna (DC) <Anna.Rathbun@lw.com>; Haviland, Graham (DC) <Graham.Haviland@lw.com>; Cremer, John (DC) <John.Cremer@lw.com>; Orlady, Will (CC) <Will.Orlady@lw.com>; Borah, Rashmi (DC) <Rashmi.Borah@lw.com>; Johnson, Michele (OC) <michele.johnson@lw.com>; John.Kozikowski@finnegan.com; #C-M Sarepta - Nippon - LW TEAM <SareptaNippon.LWTEAM@lw.com>
Cc: NS District Court <NSDistrictCourt@morganlewis.com>
Subject: RE: NS/Sarepta, No. 1:21-cv-01015-JLH - Follow-Up To Yesterday's Meet and Confer

Reba,

Attached are NS and NS Pharma's revisions to the PTO and supporting documents shown in redline. Please let me know if there are any documents that require further revisions and that are not attached here.

Are you available to meet and confer on NS's motion to strike Jarozs's testimony either before or after our meet and confer on Thursday or Friday morning?

Best regards,
Amanda

Amanda S. Williamson
Morgan, Lewis & Bockius LLP
110 North Wacker Drive, Suite 2800 | Chicago, IL 60606-1511
Direct: +1.312.324.1450 | Main: +1.312.324.1000 | Fax: +1.312.324.1001
Assistant: Eman Abulhab | +1.312.324.1455 | eman.abulhab@morganlewis.com
amanda.williamson@morganlewis.com | www.morganlewis.com

From: Rebecca.Rabenstein@lw.com <Rebecca.Rabenstein@lw.com>
Sent: Monday, November 18, 2024 3:42 PM
To: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>; JBlumenfeld@morrisnichols.com; BChard@morrisnichols.com; charles.lipsey@finnegan.com; William.Raich@finnegan.com; Alissa.Lipton@finnegan.com; Michael.Morin@lw.com; David.Frazier@lw.com; Ernest.Yakob@lw.com; mdellinger@morrisnichols.com; Derek.McCorquindale@finnegan.com; michael.flibbert@finnegan.com; Yoonhee.Kim@finnegan.com; Yoonjin.Lee@finnegan.com; Ryan.O'Quinn@finnegan.com; scott.burwell@finnegan.com; John.Williamson@finnegan.com; Kaitlyn.Pehrson@finnegan.com; Amanda.Reeves@lw.com; Anna.Rathbun@lw.com; Graham.Haviland@lw.com; John.Cremer@lw.com; Will.Orlady@lw.com; Rashmi.Borah@lw.com; michele.johnson@lw.com; John.Kozikowski@finnegan.com; SareptaNippon.LWTEAM@lw.com
Cc: NS District Court <NSDistrictCourt@morganlewis.com>
Subject: RE: NS/Sarepta, No. 1:21-cv-01015-JLH - Follow-Up To Yesterday's Meet and Confer

[EXTERNAL EMAIL]
Amanda,

EXHIBIT B

UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

Case No. 1:21-cv-01015-GBW

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA,

Defendant and Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD., and NS PHARMA, INC.,

Plaintiff and Counter-Defendants.

EXPERT REPORT AND DISCLOSURE OF MARK J. HOSFIELD

Submitted September 8, 2023

HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL EYES ONLY

Table of Contents

Table of Exhibits and Appendices

I. Background and Experience

I am currently a Managing Director at Stout. I was previously a Partner at Coopers & Lybrand, Arthur Andersen, KPMG LLP and, most recently, was a founding Principal of Davis & Hosfield Consulting LLC. Since 1987, I have focused on providing consulting and expert witness assistance to clients in commercial disputes. Prior to that, I gained financial management and operational experience as both a Controller and Vice President of Finance of a corporation, as well as in the consulting practice at Coopers & Lybrand. I am a certified public accountant and certified management accountant. I have also taught accounting classes and have lectured on finance and accounting topics.

I have performed a variety of economic, business, and financial analyses on behalf of clients in disputes, including breach of contract, lost profits, trademark and patent infringement, business valuation, construction cost and delay claims, lender liability, post-acquisition, computer software failure, economic damages in personal injury, wrongful death, employment discrimination and wrongful termination, and financial misrepresentation. I have testified as an expert witness at deposition and trial in both state and federal courts, as well as at arbitrations.

A complete description of my background and qualifications is set forth in my curriculum vitae and list of testimony, which is attached as Exhibit 1.

II. Scope of Retention

The above-referenced matter relates to, among other things, patent infringement allegations made by Nippon Shinyaku Co., Ltd. ("NS Japan") against Sarepta Therapeutics, Inc. ("Sarepta") of the following patents, each entitled "Antisense Nucleic Acids:"[1]

[1] Second Amended Complaint for Breach of Contract, Declaratory Judgment of Patent Invalidity, and Patent Infringement, dated January 14, 2022, pp. 2 and 24-37; Nippon Shinyaku Co. Ltd.'s Amended Final Infringement Contentions, dated July 27, 2023, p. 2; Memorandum Opinion, dated July 3, 2023, p. 2; U.S. Patent No. 10,385,092 entitled "Antisense Nucleic Acids," issued August 20, 2019; U.S. Patent No. 10,407,461 entitled "Antisense Nucleic Acids," issued September 10, 2019; U.S. Patent No. 10,487,106 entitled "Antisense Nucleic Acids," issued November 26, 2019; U.S. Patent No. 10,647,741 entitled "Antisense Nucleic Acids," issued May 12, 2020; U.S. Patent No. 10,662,217 entitled "Antisense Nucleic Acids," issued May 26, 2020; U.S. Patent No. 10,683,322 entitled "Antisense Nucleic Acids," issued June 16, 2020. NS Japan had previously asserted U.S. Patent No. 9,708,361 entitled "Antisense Nucleic Acids," issued July 18, 2017 (see Second Amended Complaint for Breach of Contract, Declaratory Judgment of Patent Invalidity, and Patent Infringement, dated January 14, 2022, pp. 2 and 22-24). I understand that NS Japan has subsequently withdrawn its infringement allegations as it relates to that patent.

- [redacted]

Other

- [redacted]

We have also held discussions with the following individuals:

NS Japan/NS Pharma

- [redacted]

In addition, we also spoke with Jonathan Strober, M.D., NS Japan's technical expert.

C. The NS Patents-in-Suit

The NS patents-in-suit are jointly owned by NS Japan and NCNP,[112] and all trace back to PCT/JP2011/070318, which was filed on August 31, 2011, and which claims priority to Japanese Patent Application No. 2010-196032, which was filed on September 1, 2010.[113] The NS patents-in-suit "generally relate to a morpholino antisense oligomer that induces skipping of exon 53 of the human dystrophin gene to treat [DMD]."[114] According to the NS patents-in-suit, "[a]s a result of detailed studies of the structure of the dystrophin gene, the present inventors have found that exon 53 skipping can be induced with a high efficiency by targeting [a particular sequence] in the dystrophin gene with antisense oligomers."[115] "The antisense oligomer of the [] invention can induce exon 53 skipping in the human dystrophin gene with a high efficiency. In addition, the symptoms of [DMD] can be effectively alleviated by administering the pharmaceutical composition of the [] invention."[116]

NS Japan has asserted three types of claims against Sarepta: product claims (the '092 patent, the '461 patent, and the '106 patent); method of use claims (the '741 patent and the '217 patent); and method of making claims (the '322 patent).[117]

D. NS Japan Agreements Related to VILTEPSO

NS Japan has entered into several agreements related to the distribution and sale of VILTEPSO, which I discuss in detail below.

---

[112] [redacted]

[113] U.S. Patent No. 10,385,092 entitled "Antisense Nucleic Acids," issued August 20, 2019 (Cross Reference to Related Applications); U.S. Patent No. 10,407,461 entitled "Antisense Nucleic Acids," issued September 10, 2019 (Cross Reference to Related Applications); U.S. Patent No. 10,487,106 entitled "Antisense Nucleic Acids," issued November 26, 2019 (Cross Reference to Related Applications); U.S. Patent No. 10,647,741 entitled "Antisense Nucleic Acids," issued May 12, 2020 (Cross Reference to Related Applications); U.S. Patent No. 10,662,217 entitled "Antisense Nucleic Acids," issued May 26, 2020 (Cross Reference to Related Applications); U.S. Patent No. 10,683,322 entitled "Antisense Nucleic Acids," issued June 16, 2020 (Cross Reference to Related Applications).

[114] Memorandum Opinion, dated July 3, 2023, p. 2.

[115] See, for example, U.S. Patent No. 10,385,092 entitled "Antisense Nucleic Acids," issued August 20, 2019 (Disclosure of the Invention).

[116] See, for example, U.S. Patent No. 10,385,092 entitled "Antisense Nucleic Acids," issued August 20, 2019 (Disclosure of the Invention).

[117] Nippon Shinyaku Co. Ltd.'s Amended Final Infringement Contentions, dated July 27, 2023, p. 2

i. [redacted]

As noted above, [redacted]. These parties are subject to an agreement whereby [redacted].[118] According to the terms of the agreement [redacted][119] NS Japan would also [redacted].[120] [redacted]"[121] [redacted][122]

[redacted]

[redacted]

[redacted]

According to the agreement, [redacted] This agreement also noted that [redacted] The parties also noted that [redacted].[125]

ii. [redacted]

In November 2020, [redacted] Under the terms of this memorandum, [redacted] As it relates to [redacted],

[redacted]

[redacted]

iii. [redacted]

Effective April 1, 2020, [redacted]

128 [redacted]

[redacted]

[redacted]

---

135 [redacted]

[redacted]

iv. [redacted]

[redacted]

v. [redacted]

[redacted]

[redacted]

[redacted]

vi. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

vii. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

E. Sarepta Agreements Related to VYONDYS 53

Sarepta has entered into several license agreements under which it pays royalties on sales of VYONDYS 53. Specifically, [redacted] I discuss agreements involving these parties below.

i. UWA / Sarepta Exclusive License Agreement – November 24, 2008

In November 2008, UWA and Sarepta[186] entered into an Exclusive License Agreement for certain patents right and technical information owned by UWA.[187] More specifically, UWA granted Sarepta an "exclusive, worldwide license, with the right to grant sublicenses . . . to conduct research in the Field of Use using the Patent Rights and the Technical Information and to develop, use, make, have made, practice, import, carry

[181] [redacted]

[186] The named "Licensee" in this agreement is Avi BioPharma, Inc. As noted above, prior to July 2012, Sarepta was known as AVI BioPharma, Inc (see https://investorrelations.sarepta.com/news-releases/news-release-details/avi-biopharma-announces-corporate-name-change-sarepta; Deposition of Joseph Zenkus, dated July 25, 2023, p. 90). For the purposes of discussing this agreement, I will use "Sarepta" to refer to Avi BioPharma, Inc.

[187] [redacted] Exclusive License Agreement between The University of Western Australia and Avi BioPharma, Inc., dated November 24, 2008 (SRPT-VYDS-0154831-SRPT-VYDS-0154862).

[redacted]

****

My report, with supporting exhibits, is contained herein, and presents a summary of my opinions and the bases and reasons therefor as of this date. To the extent any additional information is produced by the parties or their experts, I will be prepared to incorporate any such additional information into my report, or otherwise to amend or supplement my report as appropriate.

This report is to be used only for the purpose of this litigation and may not be published or used for any other purpose without prior written consent.

By:

Mark J. Hosfield
September 8, 2023

[594] Exhibit 7, Schedules 1 and 2.

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	**C.A. No. 21-1015-GBW** **OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	

OPENING EXPERT REPORT OF JOHN C. JAROSZ

September 8, 2023

TABLE OF CONTENTS

I. INTRODUCTION AND QUALIFICATIONS

A. Assignment

1. I, John C. Jarosz, submit this expert report on behalf of Sarepta Therapeutics, Inc. ("Sarepta") and the University of Western Australia ("UWA") (collectively, "Counter-Plaintiffs"). I have been asked by Counsel for Counter-Plaintiffs to provide expert analysis and testimony, if necessary, related to the appropriate remedy for the damage sustained by Counter-Plaintiffs due to the alleged infringement by Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") and NS Pharma, Inc. ("NS Pharma") (collectively, "Counter-Defendants" or "NS") of U.S. Patent Nos. 9,994,851 ("the '851 patent"), 10,227,590 ("the '590 patent"), and/or 10,266,827 ("the '827 patent") (collectively, "UWA Patents" or the "Counterclaim Patents-in-Suit").[1]

2. For the purposes of this report, I have assumed that at least one asserted claim of at least one of the Counterclaim Patents-in-Suit will be found valid, enforceable, and infringed. This report is based on the information that was available to me as of the date of this report and summarizes the opinions that I have formed to date. I may revise, supplement, or expand my opinions, if necessary and allowed, based on the review and analysis of information provided to me subsequent to the filing of this report.

B. Qualifications

3. I am a Managing Principal of Analysis Group, Inc. ("AG") and Director of the firm's Washington, D.C. office. AG is an economic, financial, healthcare, and strategy consulting

[1] Defendant Sarepta Therapeutics, Inc.'s Second Amended Answer, Defenses, and Counterclaims to Plaintiff Nippon Shinyaku Co., Ltd.'s Second Amended Complaint, August 16, 2023, ("Counterclaims Complaint"), at pp. 2, 36-43.

is no per se rule barring reference to settlements simply because they arise from litigation."[256] In addition, according to Michael Chapman, "settlement and non-settlement licenses share a number of fundamental similarities; the most important similarity is that both types of license are the product of arm's-length negotiations between independent parties pursuing their best interests during negotiation," and "both kinds of licenses provide useful insight into how parties in a hypothetical negotiation would determine an adequate and fair level of compensation for infringement of the patent-at-issue."[257]

a. Sarepta Licenses

(i) UWA-Sarepta License Agreement ("UWA-Sarepta License")

a) 2008 Exclusive License Agreement ("UWA-Sarepta 2008 License")

138. On November 24, 2008, UWA and Sarepta entered into an agreement whereby UWA granted Sarepta an exclusive, worldwide license to conduct research for the treatment of DMD through exon skipping using the UWA Patent Rights,[258] which included International PCT Patent Application No. PCT/AU2005/000943,[259] all corresponding patents and/or patent applications in any other country, all national phases, divisions, continuations, continuations-in-part, reissues, reexaminations, supplementary protection certifications and extensions thereof, and

[256] *AstraZeneca AB v. Apotex Corp.,* 782 F.3d 1324, 1424 (Fed. Cir. 2015). *See also Tyco Healthcare Group LP v. E-Z-EM, Inc.,* Case No. 2:07-CV-262, 2010 WL 774878, *2 (E.D. Tex. Mar. 2, 2010); *ResQNet.com, Inc. v. Lansa, Inc.,* 594 F.3d 860, 873-875 (Fed. Cir. 2010); *LaserDynamics, Inc. v. Quanta Comput., Inc.,* 694 F.3d 51, 77 (Fed. Cir. 2012).

[257] Chapman, Michael J., "Using Settlement Licenses in Reasonable Royalty Determinations," *IDEA-The Intellectual Property Law Review*, Vol. 49, No. 3 (2009): 313-357, at 357.

[258] UWA had previously entered into a Patent Assignment Agreement with SmithKline Beecham Corporation ("GSK") in March 2006 for the Patent Rights, but as of November 24, 2008 GSK had reassigned the Patent Rights to UWA. SRPT-VYDS-0154831-862, at 831, 859-862.

[259] I understand that each of the Counterclaim Patents-in-Suit claim priority to PCT/AU2005/000943. *See* U.S. Patent No. 9,994,851; U.S. Patent No. 10,227,590; U.S. Patent No. 10,266,827.

any patent that issues thereon.[260] The agreement defined the Field of Use to cover "the treatment of Duchenne Muscular Dystrophy by inducing the skipping of the Exons of Interest[261] and/or by skipping blocks of exons that include any or all of the Exons of Interest through the use of those antisense sequences listed in the Patent Rights."[262] Additionally, the license included a right for Sarepta to sublicense or assign rights consistent with the agreement.[263]

139. Under the license, Sarepta agreed to pay UWA an upfront license fee of $12,500[264] and running royalties of 0.75 percent of net sales[265] in the U.S. and 1.25 percent of net sales outside of the U.S.[266] Additionally, Sarepta agreed to pay UWA certain Milestone Fees associated with corresponding Milestone Events, including $10,000 upon initiation of a Phase II Trial of Product, $15,000 upon initiation of a Phase III Trial of Product, $20,000 upon submission of an NDA to the FDA or equivalent in the European Union for market approval of a Product, and $30,000 upon

260 SRPT-VYDS-0154831-862, at 831, 851, 833. *See also* Tab 16.

261 Exons of Interest is defined as dystrophin exons 51, 45, 44, 53, 46, 50, 8 and/or 52. SRPT-VYDS-0154831-862, at 832.

262 SRPT-VYDS-0154831-862, at 832. *See also* Tab 16.

263 SRPT-VYDS-0154831-862, at 835.

264 Sarepta also agreed to pay UWA up to $25,000 for any payment UWA made to GSK for the reassignment of the Patent Rights. *See* SRPT-VYDS-0154831-862, at 837.

265 Net sales is defined as the total invoiced sales price received for Products less (a) sales taxes or other taxes, (b) actual shipping and insurance costs, (c) actual rebates, credits, or refunds for returned or defective Products, (d) trade discounts and quantity discounts or retroactive price reductions, (3) rebates, credits, and chargeback payments actually granted to managed health care organizations, wholesalers, or to federal, state/provincial, local and other governments, including their agencies, purchasers, and/or reimburses, or to trade customers, and (f) any import or export duties, tariffs, or similar charges incurred with respect to the import or export of Products. SRPT-VYDS-0154831-862, at 832-833. Products is defined as "any human therapeutics, diagnostics…bioinformatics and any other human health care products and/or services in the Field of Use utilizing…any of the Patent Rights or technical Information." SRPT-VYDS-0154831-862, at 833.

266 SRPT-VYDS-0154831-862, at 837-838. I understand that as of the UWA-Sarepta 2008 License, if the Valid Claims do not provide a meaningful ability for Sarepta to exclude from the marketplace other products that cause skipping of the same dystrophin exon, then the royalty rate shall be reduced to 0.50 percent of net sales in the U.S. and 0.75 percent of net sales outside of the U.S. SRPT-VYDS-0154831-862, at 838. I understand that this language was superseded in the 2013 Amended and Restated License and no longer applies to the current license terms between UWA and Sarepta.

approval of an NDA or equivalent in the European Union allowing commercialization of the Product.[267]

b) 2013 Amended and Restated Exclusive License Agreement ("UWA-Sarepta 2013 Amended and Restated License")

140. On April 10, 2013, UWA and Sarepta entered into an Amended and Restated Exclusive License Agreement.[268] Under the agreement, the parties expanded the prior License Rights to define the Field of Use as "the treatment of muscular dystrophies arising from defects in the dystrophin gene or in the transcription or translation thereof, including without limitation Duchenne and Becker Muscular Dystrophies."[269] The 2013 Amended and Restated License included [redacted][270] The exclusive and worldwide license allowed UWA to retain the right to conduct non-commercial research, as well as all rights outside of the Field of Use.[271]

141. In consideration of the agreement, Sarepta agreed to pay UWA a one-time upfront license fee of [redacted] and a one-time fee for patent filing costs of [redacted][272] Additionally, Sarepta agreed to pay royalty fees equal to [redacted] of net sales on a product-by-product and country-by-country basis.[273] The agreement included a Royalty Purchase clause, which stated that Sarepta could choose to terminate its obligation to pay royalties to UWA prior to April 1, [redacted], by agreeing to pay to UWA (i) a one-time Royalty Purchase Upfront Payment of [redacted]; (ii) a one-time payment of [redacted] the first time that net sales exceed [redacted] in any

267 SRPT-VYDS-0154831-862, at 839.
268 SRPT-VYDS-0154863-889. *See also* Tab 16.
269 SRPT-VYDS-0154863-889, at 863-864.
270 Tab 16. *See also* SRPT-VYDS-0154863-888, at 885-887.
271 SRPT-VYDS-0154863-889, at 866.
272 SRPT-VYDS-0154863-889, at 870. Sarepta also agreed to pay a [redacted] license maintenance fee on each of the second, third and fourth anniversaries of the agreement date. SRPT-VYDS-0154863-889, at 870.
273 SRPT-VYDS-0154863-889, at 871.

calendar year prior to January 1, [redacted]; and (iii) a one-time payment of [redacted] the first time net sales exceed [redacted] in any calendar year prior to January 1, [redacted].[274]

c) 2016 First Amendment to License Agreement ("UWA-Sarepta 2016 Amendment")

142. On June 19, 2016, UWA and Sarepta agreed to a First Amendment to License Agreement which amended the Royalty Purchase clause.[275] Specifically, the amendment waived Sarepta's obligation to pay the [redacted] of net sales royalty on the first [redacted] million of net sales that immediately follow the first regulatory approval or a Product in the U.S., paying instead a one-time payment of $7.0 million.[276] The amendment also changed the Royalty Purchase Upfront Payment from [redacted] to [redacted].[277]

(ii) [redacted]

143. [redacted]

[274] SRPT-VYDS-0154863-889, at 871-872.
[275] SRPT-VYDS-0154890-894, at 890. *See also* Tab 16.
[276] SRPT-VYDS-0154890-894, at 890.
[277] SRPT-VYDS-0154890-894, at 890-891.
[278] SRPT-VYDS-0206683-707. *See also* Tab 16.
[279] SRPT-VYDS-0206683-707, at 686-687.
[280] SRPT-VYDS-0206683-707, at 688.

[redacted]

144. [redacted]

145. [redacted]

281 SRPT-VYDS-0206683-707, at 690. [redacted] SRPT-VYDS-0206683-707, at 690.

282 SRPT-VYDS-0206683-707, at 684, 693.

283 SRPT-VYDS-0206683-707, at 690-691. [redacted] SRPT-VYDS-0206683-707, at 691.

284 SRPT-VYDS-0206683-707, at 691.

285 SRPT-VYDS-0206683-707, at 691. [redacted] SRPT-VYDS-0206683-707, at 691.

[redacted]

(iii) [redacted]

147. [redacted]

286 SRPT-VYDS-0206683-707, at 692. [redacted] SRPT-VYDS-0206683-707, at 692-693.
287 SRPT-VYDS-0206683-707, at 687.
288 SRPT-VYDS-0206683-707, at 687.
289 SRPT-VYDS-0207092-177. *See also* Tab 16.
290 [redacted]
291 SRPT-VYDS-0207092-177, at 097-098, 100, 103. [redacted] *See* SRPT-VYDS-0207092-177, at 140-171.

251. In scenario 2, reasonably royalty damages are appropriate for worldwide VILTEPSO® sales. Those damages are [redacted][438]

252. My analysis only calculates U.S. lost profits and reasonable royalty damages through April 2023 and O.U.S. reasonable royalty damages through May 2023, which is reflective of the data available to me as of the date of this report. I will update my analysis, if allowed, to incorporate additional data made available as of trial.

253. Assuming liability is established at trial, an on-going royalty may be appropriate to compensate Sarepta for losses associated with the continued sale of VILTEPSO® between May 14, 2024 (after the expected trial date) and June 28, 2025 (the expiration of the Counterclaim Patents-in-Suit). At the point at which an on-going royalty is deemed to be appropriate, I am prepared to provide my opinion on what that should be.

John C. Jarosz
September 8, 2023

[438] Tab 3.

EXHIBIT D

UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

Case No. 1:21-cv-01015-JLH

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA,

Defendant and Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC.,

Plaintiff and Counter-Defendants.

SECOND SUPPLEMENTAL EXPERT REPORT AND DISCLOSURE OF MARK J. HOSFIELD

Submitted November 5, 2024

HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL EYES ONLY

Table of Contents

Table of Exhibits and Appendices

I. Introduction

I previously submitted an Expert Report and Disclosure, dated September 8, 2023 ("Opening Report"), a Rebuttal Expert Report and Disclosure, dated October 11, 2023 ("Rebuttal Report"), Reply Expert Report and Disclosure, dated October 27, 2023 ("Reply Report"), a Supplemental Expert Report and Disclosure, dated April 12, 2024 ("Supplemental Report"), and a Supplemental Rebuttal Expert Report and Disclosure, dated April 19, 2024 ("Supplemental Rebuttal Report") for the above-referenced matter. The purpose of this Second Supplemental Report is to update my lost profits and reasonable royalty damages calculations related to Nippon Shinyaku's claims against Sarepta to reflect supplemental financial information produced by the parties, and to estimate my damages calculations through the start of trial in this matter. I incorporate my prior reports by reference as part of this Second Supplemental Report.

II. New Information Relied Upon

My opinions are based upon information available to me as of the date of this Second Supplemental Report. My prior reports identify information considered as of those report dates. Since that time, I have considered additional materials including any materials cited herein as well as those materials identified in Second Supplemental Exhibit 2 to this report. The table below summarizes certain documents used for the calculations contained in my prior reports as well as the new versions of those documents which I have used to update my calculations:[1]

[redacted]

[1] In addition to these documents, I have reviewed [redacted]

****

My Second Supplemental Report, with supporting exhibits, is contained herein, and along with my prior reports, presents a summary of my opinions and the bases and reasons therefor as of this date. To the extent any additional information is produced by the parties or their experts, I will be prepared to incorporate any such additional information into my reports, or otherwise to amend or supplement my reports as appropriate.

This report is to be used only for the purpose of this litigation and may not be published or used for any other purpose without prior written consent.

By:

Mark J. Hosfield
November 5, 2024

EXHIBIT E

UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

Case No. 1:21-cv-01015-JLH

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA,

Defendant and Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC.,

Plaintiff and Counter-Defendants.

SECOND SUPPLEMENTAL REBUTTAL EXPERT REPORT AND DISCLOSURE OF MARK J. HOSFIELD

Submitted November 12, 2024

HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL EYES ONLY

United States District Court for the District of Delaware
Case No. 1:21-cv-01015-JLH

Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.
Sarepta Therapeutics, Inc. and The University of Western Australia v. Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.

Table of Contents

Table of Exhibits

I previously submitted an Expert Report and Disclosure, dated September 8, 2023 ("Opening Report"), a Rebuttal Expert Report and Disclosure, dated October 11, 2023 ("Rebuttal Report"), Reply Expert Report and Disclosure, dated October 27, 2023 ("Reply Report"), a Supplemental Expert Report and Disclosure, dated April 12, 2024 ("Supplemental Report"), a Supplemental Rebuttal Expert Report and Disclosure, dated April 19, 2024 ("Supplemental Rebuttal Report"), and a Second Supplemental Expert Report and Disclosure, dated November 5, 2024 for the above-referenced matter ("Second Supplemental Report"). The purpose of this Second Supplemental Rebuttal Report is to update my lost profits and reasonable royalty damages calculations related to Sarepta's and UWA's claims against Nippon Shinyaku and NS Pharma to reflect supplemental financial information and additional documents produced by the parties, as well as update the numerical basis underlying my opinions regarding the commercial success of the NS patents-in-suit. I incorporate my prior reports by reference as part of this Second Supplemental Rebuttal Report.

I. New Information Relied Upon

My opinions are based upon information available to me as of the date of this Second Supplemental Rebuttal Report. My prior reports identify information considered as of those report dates. Since that time, I have considered additional materials including any materials cited herein as well as those materials identified in Supplemental Rebuttal Exhibit 2 to this report. In addition to considering the supplemental financial information, I have been asked to perform alternative calculations based on the following recently produced [redacted]:

- [redacted]

- [redacted]

Since the date of my Second Supplemental Report, I have also reviewed the Second Supplemental Opening Expert Report of Mr. Jarosz, dated November 5, 2024.

II. Updated Damages Calculations

In my Supplemental Rebuttal Report, I calculated Sarepta's/UWA's potential damages for the period of August 19, 2020 through February 2024 based on data produced by the parties, as well as extended those calculations through May 13, 2024 to be consistent with Mr. Jarosz's inclusion of estimated sales for the time period of March 1, 2024 through May 13, 2024.[1] In this report, I have updated my damages calculations to extend through August 31, 2024 based on newly produced data from the parties, and I have extended my damages calculations through December 15, 2024 to be consistent with Mr. Jarosz's additional estimated (not actual) sales for September 1, 2024 through December 15, 2024.[2]

I have also been asked to prepare an additional damages calculation based on [redacted]

[1] Supplemental Rebuttal Expert Report and Disclosure of Mark J. Hosfield, dated April 19, 2024, p. 2, Supplemental Rebuttal Exhibit 3, Schedule 1, and Supplemental Rebuttal Exhibit 4.

[2] As discussed further below, I have also extended my damages calculations through December 16, 2024 to be consistent with my damages calculations for Nippon Shinyaku as shown in my Second Supplemental Report.

[redacted].

Mr. Jarosz "ha[s] been asked to update [his] opinions regarding the appropriate damages owed by NS to [Sarepta/UWA], assuming liability is established at trial. Specifically, [he] ha[s] been asked to and did update [his] damages calculations to account for the full period August 2020 through December 15, 2024 for U.S. sales, and January 2022 through December 15, 2024 for O.U.S. sales of VILTEPSO[],"[5] based on supplemental financial information from the parties including actual data through August 31, 2024 and estimates for the time period of September 1, 2024 through December 15, 2024.

Thus, "[s]upplementing [his] damages analysis to account for the updated data, [Mr. Jarosz] find[s] that in scenario 1, lost profits damages are [redacted]

For scenario 2, Mr. Jarosz's "reasonable royalty damages are [redacted]

Mr. Jarosz has also prepared alternative damages calculations assuming that [redacted]

[3] [redacted]

[4] Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.'s Letter Brief Regarding Late Produced Licensing and No Lost Profits, dated May 7, 2024, pp. 2-3.

[5] Second Supplemental Opening Expert Report of John C. Jarosz, dated November 5, 2024, p. 2.

[6] Second Supplemental Opening Expert Report of John C. Jarosz, dated November 5, 2024, p. 3.

[7] Second Supplemental Opening Expert Report of John C. Jarosz, dated November 5, 2024, p. 3.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[45] Second Supplemental Rebuttal Exhibit 3, Schedule 1.

[46] Second Supplemental Rebuttal Exhibit 3, Schedule 1. [redacted].

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[47] Second Supplemental Rebuttal Exhibit 4.

[48] Second Supplemental Rebuttal Exhibit 4. [redacted]

[redacted]

[redacted]

[redacted]

[49] Second Supplemental Rebuttal Exhibit 3, Schedule 1.

[50] Second Supplemental Rebuttal Exhibit 3, Schedule 1. [redacted]

[redacted]

[51] Second Supplemental Rebuttal Exhibit 4.

[52] Second Supplemental Rebuttal Exhibit 4. [redacted]

[53] Second Supplemental Rebuttal Exhibit 3, Schedule 1 and Second Supplemental Rebuttal Exhibit 4.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[54] Second Supplemental Rebuttal Exhibit 3, Schedule 1 and Second Supplemental Rebuttal Exhibit 4. [redacted]

[55] Second Supplemental Rebuttal Exhibit 3, Schedule 1 and Second Supplemental Rebuttal Exhibit 4.

[redacted]

V. Commercial Success of the NS Patents-In-Suit

Additionally, as discussed in my Rebuttal Report,

> I further understand that, in order for evidence of commercial success to be relevant to the issue of obviousness, a patent owner seeking to rely on these considerations to argue non-obviousness must show a nexus between the claimed invention and the evidence of commercial success.[] I also understand that this nexus may be inferred, but only when 'the patentee shows both that there is commercial success, and that the thing . . . that is commercially successful is the invention claimed and disclosed in the patent.'[] I further understand that commercial success is relevant to the obviousness inquiry because, presumably, the 'idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.'[][57]

After considering the supplemental financial information, my opinions regarding the commercial success of the NS patents-in-suit remains the same and are further supported based on the following updated financial information relating to the sales of VYONDYS 53 which admittedly practice the NS patents-in-suit:[58]

[56] Second Supplemental Rebuttal Exhibit 3, Schedule 1 and Second Supplemental Rebuttal Exhibit 4. [redacted].

[57] Rebuttal Expert Report and Disclosure of Mark J. Hosfield, dated October 11, 2023, p. 42.

[58] I note that Nippon Shinyaku's Motion for Partial Summary Judgment on the issue of infringement of the NS patents-in-suit was granted in view of Sarepta's stipulation to infringement (see Email Re: Activity in Case 1:21-cv-01015-JLH Nippon Shinyaku, Ltd. v. Sarepta Therapeutics, Inc. Order on Motion for Partial Summary Judgment, dated May 1, 2024).

This report is to be used only for the purpose of this litigation and may not be published or used for any other purpose without prior written consent.

By:

Mark J. Hosfield

November 12, 2024